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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/065,173	09/24/2002	Michael J. Collins	1700.89C	4893
21176	7590	07/19/2005		
SUMMA & ALLAN, P.A. 11610 NORTH COMMUNITY HOUSE ROAD SUITE 200 CHARLOTTE, NC 28277			EXAMINER GAKH, YELENA G	
			ART UNIT 1743	PAPER NUMBER

DATE MAILED: 07/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/065,173	Applicant(s) COLLINS ET AL.	
	Examiner Yelena G. Gakh, Ph.D.	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

1. Amendment filed 06/09/05 is acknowledged. Claims 1-2 and 5-12 are pending in the application.

#### ***Response to Amendment***

2. The examiner introduces a new issue of the scope of enablement for the pending claims.

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-2 and 5-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for quartz or glass fiber pads and a sheet material being a perfluorinated hydrocarbon polymer, does not reasonably provide enablement for other pads and sheet materials. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The specification does not provide any examples of pads that are “hydrophilic and lipophilic and substantially transparent to microwave radiation and are free of atoms that would interfere with or mask the proton NMR response of the protons in the fats and oils in the sample” and “sheet materials that are free of atoms that would interfere with or mask NMR response of the protons in the fats and oils in the sample” other than quartz or glass fiber pads and perfluorinated hydrocarbon polymeric sheets. It would have been an unnecessary burden for any routineer in the art to search for pads and sheet materials, which would meet the requirements of claim 1. The specification does not teach or provide any guidance for methods of searching such materials. It is not clear, if searching such materials requires for any routineer in the art obtaining NMR spectra of possible materials as well as testing them for hydrophilic and

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lipophilic properties. The examiner considers such recitation of the claims as imposing an unnecessary burden on any person of ordinary skill in the art for practicing the invention.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-2 and 5-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear, what are "at least some fats and oils" recited in claim 1? Are petroleum products (which are organic) "at least some fats and oils" recited in the claim? Indefiniteness of the expression "an organic portions containing at least some fats and oils" renders claims 1-2 and 5-9 unclear and indefinite. Since it is not clear, which fats and oils are meant in the claim, this renders the limitation for the materials of the pad and sheet unclear and indefinite, as organic fats and oils of different origins may have completely different NMR spectra; this makes it unclear and indefinite as to which pads and sheet materials are meant in the claims. This renders claims 1-2, 5 and 8-12 unclear and indefinite as to what the pad is made of, and this renders claims 1-2, 5-8 and 10-12 unclear and indefinite as to which type of the sheet material the claims recite.

### ***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. **Claims 1-2, 5, 8 and 10-12** are rejected under 35 U.S.C. 102(b) as being anticipated by any sandwich made of bread, which does not contain dough conditioners (comprising lipids), and any food product comprising fat or oil (butter, meat, fish, etc.) and wrapped in any conventional polyvinyl chloride (PVC) plastic wrap, as evidenced by Roudaout et al. (J. Cereal Sci., 1998), Alanen et al. (Phys. Med. Biol., 1991) and Pourahmady (US 5,292,823).

Roudaout teaches NMR study of “mobility of lipids in low moisture bread”, which indicates that there is no interference between the NMR signals of fat (lipids) and all other bread ingredients. Therefore, the bread, which does not comprise such lipids, meets the requirements of the substrate of claims 1-2, 5, 8 and 10-12.

Alanen teaches that the fat proton signals are at ~ 1 ppm (see page 954), while Pourahmady teaches that PVC signals are at lower fields than 3.5 ppm, and therefore do not interfere with the fat signals; it means that PVC wrap satisfied the limitation of claim 1 for the wrap.

### ***Response to Arguments***

9. Applicant's arguments filed 06/09/05 have been fully considered but they are not persuasive.

Regarding rejections under 35 U.S.C. 112, second paragraph. The examiner does not question the clarity of the terms “fats” and “oils” in general. The examiner asks as to what type of organic fats and oils are meant in the claims, since the fats and oils can have completely different origin, e.g. being obtained from petroleum products or from food products. The origin of the fats and oils define the pad and sheet materials according to the claims. Since the origin of the fats and oils is not defined, it is not clear, which pads and sheet materials can be used for the claimed NMR sample, which renders the claims unclear and indefinite. Regarding the pads and sheet materials. It is not quite apparent to the examiner, how the discussion of NMR principles relates to the pad and sheet materials of the pending claims. The principles of NMR can be found in any textbook. The question is, how a routineer in the art can find the pads and sheet materials satisfying conditions of the pending claims, if only very specific materials are disclosed in the specification, which are not recited in the broad claims? The specification does not provide any guidance of how to search for other materials besides those specifically listed in the specification. This not only renders claims unclear and indefinite, but also imposes an issue of the scope of enablement, which the examiner raises in the present Office action.

Regarding rejection over the prior art. The examiner would like to direct the Applicants' attention to MPEP § 2131.01:

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**"2131.01 Multiple Reference 35 U.S.C. 102 Rejections**

Normally, only one reference should be used in making a rejection under 35 U.S.C. 102.

**However, a 35 U.S.C. 102 rejection over multiple references has been held to be proper when the extra references are cited to:**

- (A) Prove the primary reference contains an "enabled disclosure;"**
- (B) Explain the meaning of a term used in the primary reference; or**
- (C) Show that a characteristic not disclosed in the reference is inherent.**

See paragraphs I-III below for more explanation of each circumstance.

**I. TO PROVE REFERENCE CONTAINS AN "ENABLED DISCLOSURE"**

**Extra References and Extrinsic Evidence Can Be Used To Show the Primary Reference Contains an "Enabled Disclosure"**

When the claimed composition or machine is disclosed identically by the reference, an additional reference may be relied on to show that the primary reference has an "enabled disclosure." In re Samour, 571 F.2d 559, 197 USPQ 1 (CCPA 1978) and In re Donohue, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985) (Compound claims were rejected under 35 U.S.C. 102(b) over a publication in view of two patents. The publication disclosed the claimed compound structure while the patents taught methods of making compounds of that general class. The applicant argued that there was no motivation to combine the references because no utility was previously known for the compound and that the 35 U.S.C. 102 rejection over multiple references was improper. The court held that the publication taught all the elements of the claim and thus motivation to combine was not required. The patents were only submitted as evidence of what was in the public's possession before applicant's invention.).

**II. TO EXPLAIN THE MEANING OF A TERM USED IN THE PRIMARY REFERENCE**

**Extra References or Other Evidence Can Be Used to Show Meaning of a Term Used in the Primary Reference**

Extrinsic evidence may be used to explain but not expand the meaning of terms and phrases used in the reference relied upon as anticipatory of the claimed subject matter. In re Baxter Travenol Labs., 952 F.2d 388, 21 USPQ2d 1281 (Fed. Cir. 1991) (Baxter Travenol Labs. invention was directed to a blood bag system incorporating a bag containing DEHP, an additive to the plastic which improved the bag's red blood cell storage capability. The examiner rejected the claims over a technical progress report by Becker which taught the same blood bag system but did not expressly disclose the presence of DEHP. The report, however, did disclose using commercial blood bags. It also disclosed the blood bag system as "very similar to [Baxter] Travenol's commercial two bag blood container." Extrinsic evidence (depositions, declarations and Baxter Travenol's own admissions) showed that commercial blood bags, at the time Becker's report was written, contained DEHP. Therefore, one of ordinary skill in the art would have known that "commercial blood bags" meant bags containing DEHP. The claims were thus held to be anticipated.).

**III. TO SHOW THAT A CHARACTERISTIC NOT DISCLOSED IN THE REFERENCE IS INHERENT**

**Extra Reference or Evidence Can Be Used To Show an Inherent Characteristic of the**

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#### Thing Taught by the Primary Reference

"To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) (The court went on to explain that "this modest flexibility in the rule that anticipation' requires that every element of the claims appear in a single reference accommodates situations in which the common knowledge of technologists is not recorded in the reference; that is, where technological facts are known to those in the field of the invention, albeit not known to judges." 948 F.2d at 1268, 20 USPQ at 1749-50.). Note that as long as there is evidence of record establishing inherency, failure of those skilled in the art to contemporaneously recognize an inherent property, function or ingredient of a prior art reference does not preclude a finding of anticipation. *Atlas Powder Co. v. IRECO, Inc.*, 190 F.3d 1342, 1349, 51 USPQ2d 1943, 1948 (Fed. Cir. 1999) (Two prior art references disclosed blasting compositions containing water-in-oil emulsions with identical ingredients to those claimed, in overlapping ranges with the claimed composition. The only element of the claims arguably not present in the prior art compositions was "sufficient aeration . . . entrapped to enhance sensitivity to a substantial degree." The Federal Circuit found that the emulsions described in both references would inevitably and inherently have "sufficient aeration" to sensitize the compound in the claimed ranges based on the evidence of record (including test data and expert testimony). This finding of inherency was not defeated by the fact that one of the references taught away from air entrapment or purposeful aeration.). See also *In re King*, 801 F.2d 1324, 1327, 231 USPQ 136, 139 (Fed. Cir. 1986); *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 782, 227 USPQ 773, 778 (Fed. Cir. 1985). See MPEP § 2112 - § 2112.02 for case law on inherency. Also note that the critical date of extrinsic evidence showing a universal fact need not antedate the filing date. See MPEP § 2124".

As it is unambiguously indicated in the previous Office action, the references are used as evidence, exactly according to MPEP rule. The examiner slightly changes the grounds for rejection by indicating that the bread of the sandwich will not contain dough conditioners, which comprise lipids (see e.g. "Lipids: Fats, Oils, Waxes, etc." of the University of Cincinnati webpage). All other ingredients do not interfere with fat and oils NMR signals, as evidenced by Roudaout. The examiner also demonstrated by two other evidence references that a conventional polymer wrapper, Saran, would not interfere with fat and oil <sup>1</sup>H NMR signals, since the fat and oils and Saran polymer give resonances in completely different NMR regions.

Moreover, the Applicants' remarks that Saran polymer "may have" proton signals in the same region as fat and oils supports the examiner's position that the limitations of the pad and

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sheet materials in those claims, in which no particular materials are recited, render the claims unclear and indefinite; even such clear examples as those recited by the examiner, give ambiguous interpretation as to which materials can be considered suitable for the NMR samples recited in the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

7/15/05

  
**YELENA GAKH**  
**PRIMARY EXAMINER**